

In the Application Of Lacoste et al
Serial No. 10/757,703
June 5, 2007
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In the Drawings:

A corrected sheet of informal drawings for Fig.'s 5, 6, 7A and 7B is included herewith; a formal drawing sheet will be filed in due course.

REMARKS

In response to the Official Action mailed February 9, 2007, Applicant respectfully requests reconsideration, reexamination and allowance of claims 1-23 in view of the following amendments and remarks. By this amendment, Applicant has amended claims 1, 13, 15 and 19 to more clearly define the present invention.

The Office Action objects to the drawings because reference numerals indicated in the text of the application have not been shown in several of the drawings. Applicant has added reference numeral "2" in Fig. 7 as requested; and has deleted the reference to numeral "3" in the specification on page 7 (line 9) as reference numeral "3" is not depicted *per se* in Fig. 5, to which this passage of the description refers.

With respect to the objection raised in paragraph 2 of the Detailed Action, Applicant is confused as the objection is directed to Figs. 7 and 8 as Fig 8 contains no written terms, contrary to the statement in paragraph 2 of the Office Action. As the Applicant understands this objection, the concerns are in fact raised against Figs. 5-7. Applicant has therefore amended Figs. 5-7 (as well as the corresponding part of the description (page 7) *see above*) so that all terms have now been replaced by their corresponding reference numerals, as requested. Upon acceptance of the corrections by the Examiner, Applicant will prepare and file a formal replacement sheet containing amended Fig.'s 5-7.

The Office Action has rejected claims 1-3 and 8 under 35 U.S.C. § 102(b) as being anticipated by Oakley (U.S. Patent No. 5,335,663). Applicant respectfully disagrees, and as presently amended, suggests that the present invention is patently distinct from Oakley. First, the Office Action states that reference numeral 34 in Fig. 1A of Oakley discloses at least one planar transducer. Applicant disagrees with this statement. As stated in Col. 4, lines 62-65 of Oakley, on which the Office Action relies:

In a further embodiment, the first array portion includes a plurality of transducers that are oriented so as to define a substantially planar curve, i.e., a curve that lies substantially in a single plane. (emphasis added).

The Office Action has understood from the above noted passage that Oakley discloses at least one planar transducer. But clearly this is not correct. Referring to Fig. 1A of Oakley, one can

clearly see that the array of transducers has a curved portion 34 as confirmed by the specification (see col. 8, lines 22-43). However, Oakley simply uses the terms “planar curve” to indicate that the array of transducers of the curved portion 34 are arranged along a planar curve, but as shown in Fig. 1A this does not result in at least one planar transducer. In sharp contrast, the present invention, as amended, clearly includes a planar transducer. As a consequence, the objection for lack of novelty of the invention of claim 1 is not correct.

Second, Oakley discloses an ultrasonic imaging probe (see column 1, lines 7-9 and column 4, lines 47-53). However, in Oakley, the transducers are not used for coagulation and are not suitable for such a use as they neither provide sufficient ultrasound power nor the required focus of ultrasounds; in sharp contrast to the teachings of the present invention. As a consequence, the invention of claim 1 is clearly novel over Oakley for this reason. Further, there is no suggestion in the prior art for a laparoscopy probe as claimed.

Applicant suggests that as Oakley does not teach the invention of claim 1 it cannot teach the inventions shown in claims dependent thereon, specifically claims 2, 3 and 8.

The Office Action has rejected claim 13, under 35 U.S.C. § 102(b) as being anticipated by Davison (U.S. Patent No. 5,322,055). Applicant respectfully disagrees, and as presently amended, suggests that the present invention is patently distinct from Davison. As will be seen, Davison discloses an ultrasonically-actuated surgical instrument for cutting/coagulating tissue (see, column 2, lines 15-23). In Davison, blade 20 is not movable with respect to the transducer, contrary to the statement in the Office Action. It is clear from the language in Davison, specifically column 7, lines 41-49 (which was pointed out by the Examiner) that the transducer and blade 20 are rigidly linked via blade coupler extension 16 and blade coupler 18. Davison clearly states, in the cited passage, that blade coupler extension 16 is:

screw-threaded onto a stud projecting from one end of handpiece 14 and connected to the transducer whereby ultrasonic vibrations in a longitudinal direction are transmitted along extender 16 and blade coupler 18 to blade 20.

See also column 2, lines 28-35, mentioning:

[...] a piezoceramic transducer for converting such electrical signal into longitudinal mechanical vibration for coupling to a blade assembly.

As a consequence, the invention of claim 1 is novel over Davison for this first reason.

Further, Davison teaches neither an ultrasound coagulation apparatus nor an ultrasound coagulation transducer as claimed in claim 13. Indeed, in Davison, coagulation is not provided by the ultrasound transducer itself, i.e. coagulation is **not** the result of ultrasound radiations in the tissue as it is the case in the invention. Instead, in Davison, coagulation is provided by pressing or biasing the tissue to be coagulated against a high-speed vibrating blade, more precisely an ultrasonically vibrating blade under the action of an ultrasound transducer rigidly connected to the blade (as previously mentioned).

This is most clearly demonstrated at column 1, lines 6-11, which recite that the invention relates to an ultrasonic surgical instrument having a clamp for pressing or biasing tissue against an ultrasonically vibrating blade for improved cutting and coagulation. (emphasis added).

To summarize, in Davison, coagulation is caused by mechanical movement between the blade and the tissue while in the present invention, as amended, coagulation is caused by the ultrasound radiations. Furthermore, there is no suggestion in the prior art for an ultrasound coagulation apparatus as claimed.

The Office Action has rejected claims 4-7 and 9-12 as being unpatentable, under 35 U.S.C. § 103(a) over Oakley in view of Pederson (U.S. Patent No. 4,206,763). First, Applicant notes that with respect to Oakley, it has responded above noting that Oakley does not teach the invention shown in Claim 1 and, therefore, does not teach the invention of dependent claims 4-7 and 9-12. It is respectfully submitted that the teachings of Pederson do not add sufficiently to the deficiencies that Applicant has noted in Oakley to cause the present invention to be obvious in light of this combination of references.

In addition, it is worth noting that the reasoning of the Office Action is not correct. First, neither Oakley nor Pedersen deals with using an ultrasound transducer for coagulation. So, logically, the invention of the claims as presently amended involves an inventive step, if for this first reason. Second, the present invention relates to a laparoscopy probe, i.e. a probe that is inserted in the body of the patient. This is completely different from an external imaging device as is the device of Pedersen. It will be understood that a laparoscopy probe, or any device meant to enter the human body, will involve technical considerations that do not exist in an external imaging devices. Thus, those having ordinary skill in the art would not even have contemplated

Pedersen, as Pedersen is used by different types of technicians and health care workers than those who use invasive devices. It is suggested that the present invention involves an inventive step if only for this second reason.

Third, Pedersen teaches holding the breast in place, within the imaging apparatus, with the help of a vacuum, such that the ultrasonic imaging transducer can revolve around the breast to obtain complete 360° scans. This function is clearly different from the function of the channel of the claimed invention. The claimed channel aims to hold the probe in place on the organ (e.g. the kidney) by the suction effect (see description page 13, lines 8-21): this is not disclosed in Pedersen as the probe is not fixed, but revolves around the breast.

Further, the function of the vacuum in Pedersen could not be implemented for a laparoscopic probe as it would result in bringing inside of the body an apparatus in which the internal organ (such as a kidney) would be held. This is of course not possible as it would be detrimental to the patient, as is known to persons having skill in the art. Clearly, Pederson teaches away from the present invention. As a result, it is suggested that the invention of these claims involves an inventive step if only for this second reason.

The Office Action has rejected claim 14 as being unpatentable, under 35 U.S.C. § 103(a) over Davison in view of Driscoll Jr. (U.S. Patent No. 5,882,302). First, Applicant notes that with respect to Davison, it has responded above noting that Davison does not teach the invention shown in Claim 13 and, therefore, does not teach the invention of dependent claim 14. It is respectfully submitted that the teachings of Driscoll Jr. do not add sufficiently to the deficiencies that Applicant has noted in Davison to cause the present invention to be obvious in light of this combination of references.

The Office Action has rejected claims 15 and 19 as being unpatentable, under 35 U.S.C. § 103(a) over Lafon (U.S. Patent No. 6,379,320). The Office Action recognizes that the invention of claim 15 is novel over Lafon because the ultrasound transducer is used in combination with a membrane, which is contrary to the teachings of the claimed invention. However, the Office Action states that it would have been an obvious matter of design choice to remove the membrane (NB: on page 6, third paragraph, the Office Action mentions erroneously t “a transparent membrane” instead of “without membrane”). The reason for this as stated by the Office Action is that the Applicant has not disclosed that a “probe without membrane provides

an advantage, used for a particular purpose, or solves a stated problem.” The Office Action further adds that “one of ordinary skill [...] would have expected Applicant’s invention to perform equally well with probe with a thin or transparent membrane because it will prevent of blocking of emitted ultrasound pulses from the transducers.”

However, the Applicant cannot agree with the reasoning of the Office Action. In fact, one teaching of the invention is precisely the fact of making use in the coagulation instrument of an ultrasound transducer without membrane. In prior references, and notably in Lafon, the ultrasound transducer is always used with a membrane. The membrane is used for retaining the coupling/cooling liquid in order to ensure among others that the liquid will provide for ultrasound coupling between the transducer and the membrane and in turn the tissues of the body in contact with the membrane (see column 5, lines 27-40). It was known in the art that such a membrane has some opacity to ultrasounds. If the membrane is quite thick, the membrane has good mechanical strength well suited for endoscopic applications, but its opacity is increased as a consequence of its thickness. On the other hand, if the membrane is thin and flexible, providing very low opacity to ultrasound, the membrane will have low mechanical strength and will have to be changed after each use, as is known.

The issue of opacity is further exasperated when ultrasounds are used for treating (such as coagulating) with respect to imaging. Because as the opacity of the membrane is increased with the power of the ultrasounds, a cavitation effect causes micro-bubbles to occur at the membrane which is further yield by a cascade or cataract effect.

Although the disadvantage of a membrane (opacity to ultrasound) is known, persons having ordinary skill in the art have never thought to use ultrasound transducers without a membrane, and would never have attempted to do so. Indeed, in the prior art, the membrane was believed to be absolutely necessary in view of its function, i.e. retaining the cooling/coupling liquid for ensuring correct ultrasound coupling and cooling.

As presently claimed, the invention teaches against this technical prejudice because the inventors have recognized that notably in endoscopic applications it is possible to use the transducer without membrane. Cooling/coupling liquid is still used for the same reasons as in the prior art, but it flows continuously between the transducer and the tissue in the body to be treated.

This is shown in the present invention, see page 6, lines 1-5, explaining:

The absence of a membrane facilitates insertion and improves coupling with the organ or tissue to be treated by eliminating one interface and ensuring that the liquid extends continuously between the transducer and the tissue. All windowing is also avoided so that vision (in the case of endoscopy) is not limited; nor is the treatment region limited by a window.

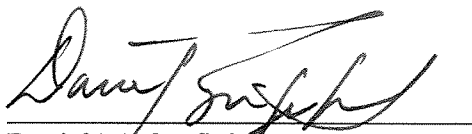
As a result, the invention of claims 15 and 19 involves an inventive step over the prior art.

Claims 16-18 and claims 20-23 are dependent upon claims 15 and 19 respectively, and therefore, it is suggested that they are patentable too.

In view of the foregoing remarks and amendments, it is believed that the subject application is now in condition for allowance, and an early Notice of Allowance is respectfully requested.

Applicant encloses herewith a petition for a one month extension of time in which to file this response as well as authorizing the payment of the fee by deposit account (No. 23-0920). It is believed that no other fee is needed, however, should it be determined that any fees are necessary the Commissioner is hereby authorized to charge any additional fee which may be required for this application under 37 C.F.R. §§ 1.16-1.18, including but not limited to the issue fee, or credit any overpayment, to Deposit Account No. 23-0920. Further, should any petition be required with respect to this reply and amendment, the Commissioner is respectfully requested to treat this paper as the necessary petition or petitions and to charge the petition fee(s) to the above noted deposit account.

Respectfully submitted



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